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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BEKKER, KELLY JO	

ART UNIT	PAPER NUMBER
1781	

NOTIFICATION DATE	DELIVERY MODE
11/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No.	Applicant(s)	
	10/564,599	SECRETIN, MARIE-CHRISTINE	
	Examiner	Art Unit	
	KELLY BEKKER	1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *15-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Amendments made June 18, 2010 have been entered;
Claims 1-25 remain pending;
Claims 15-21 have been withdrawn from consideration.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 112 second paragraph rejection of claim 14 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, due to the term "low amount of electrolytes" has been withdrawn in light of applicant's amendments made June 18, 2010.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The 103(a) rejection of claims 1-3, 5, 6, 8, 10-14, and 22-25 as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) has been withdrawn in light of applicant's amendments made June 18, 2010; specifically the references do not teach a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1 and an NA/K ratio around 0.4mmol as recited in claim 14.

The 103(a) rejection of claims 4 and 7 as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1), further in view of the combination of Holm, Finn (Gut Health November 2001 pages 1-28) and Ishibashi et al (Bifidobacteria: their significance in human intestinal health Mal J Nutr 3, pages 149-159, 1997) has been withdrawn in light of applicant's amendments made June 18, 2010; specifically the references do not teach a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1.

The 103(a) rejection of claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP

0904784 A1), further in view of Kratky et al (EP 01048226 A1) has been withdrawn in light of applicant's amendments made June 18, 2010; specifically the references do not teach a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1.

The 103(a) rejection of claims 1-3, 5, 6, 9-14, and 22-25 as being unpatentable over Kratky et al (EP 01048226 A1) in view of Van Hoey-De-Boer et al (EP 0904784 A1) has been withdrawn in light of applicant's amendments made June 18, 2010; specifically the references do not teach a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1 and an NA/K ratio around 0.4mmol as recited in claim 14.

The 103(a) rejection of claims 4 and 7 as being unpatentable over Kratky et al (EP 01048226 A1) in view of Van Hoey-De-Boer et al (EP 0904784 A1), further in view of the combination of Holm, Finn (Gut Health November 2001 pages 1-28) and Ishibashi et al (Bifidobacteria: their significance in human intestinal health Mal J Nutr 3, pages 149-159, 1997) has been withdrawn in light of applicant's amendments made June 18, 2010; specifically the references do not teach a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1.

Claims 1-3, 5, 6, 8, 10-14, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1).

Kuslys et al (Kuslys) teaches of an infant formula (page 2 lines 15-16) comprising a source of lipids comprising fish oil (page 6 lines 14-23) which includes the Long Chain Polyunsaturated Fatty Acid (LC-PUFA) comprising docosahexaenoic acid (DHA), a source of carbohydrates (page 6 lines 6-13), a source of sweet whey protein which is modified by the removal of the casino-glyco-macropeptide (CGMP) (page 2 lines 35 and 36) wherein the protein is at about 1.8g/100kcal (page 3 lines 5-9), other beneficial substances (page 7 lines 28-29), water, and salts which when combined with water formed electrolytes, including sodium, calcium, magnesium, chloride, and potassium (page 7 lines 12-22 and page 8 lines 1-2). Kuslys teaches that the ratio of whey protein

to casein is from 60-70% whey to 30-40% casein, thus teaching that the protein encompasses 60-70% whey protein (page 3 lines 27-32). Page 9 lines 21-25, Kuslys teaches that the whey protein comprises about 33-86% of the total protein (6% whey protein/(6% whey protein +10% non-fat milk solids + 2% alpha lactalbumin rich whey protein source); 50% whey protein/(50% whey protein +8% non-fat milk solids + 0% alpha lactalbumin rich whey protein source)). As hydrolysis is the process of breaking down a molecule and Kuslys teaches that the proteins are not hydrolyzed or treated by any other break down process, one of ordinary skill in the art would expect that the non hydrolyzed proteins as taught by Kuslys are intact as recited in claim 8. Kuslys teaches that in another embodiment, the proteins are hydrolysed. Refer specifically to page 3 lines 21-22.

Kuslys is silent to the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobaceria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG as recited in claim 5, to the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1, and an Na/K ratio of around 0.4mmol as recited in claim 14.

Van Hoey-De-Boer et al (Hoey) teaches that an infant formula with health promoting action is formed with probiotics Bifidobacterium including Bifidobacterium Longum (B. longum) and a Lactobacillus strain including Lactobacillus rhamnosus GG (Lactobacillus paracasei rhamnosus GG) (abstract and paragraphs 0004, 0005, 0014, and 0018). Hoey teaches that the preparation aids in the prevention and treatment of disorders of the gastrointestinal tract (paragraph 0001).

Wilson teaches of a nutritional composition for inclusion in infant formulas (abstract and paragraph 0018). Wilson teaches that infant formulas suitable for use should contain all vitamins and minerals considered to be essential in the daily diet (paragraph 0019). Wilson teaches that a preferred infant formula comprises 460mg of calcium and 333mg of phosphorus and thus a calcium to phosphorus weight ratio of about 1.4 and 160mg of sodium which is about 6.96mmol of sodium and 650mg of

potassium which is about 16.62mmol of potassium, and thus an Na/K ratio of about 0.4mmol (paragraph 0020).

Regarding the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobaceria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the probiotics Bifidobaceria and Lactobacillus paracasei rhamnosus GG in the composition of Kuslys in view of Hoey in order to form an infant formula which aids in the prevention and treatment of disorders of the gastrointestinal tract as taught by Hoey, thus promoting better infantile health.

Regarding the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 and an Na/K ratio of around 0.4mmol, it would have been obvious to one of ordinary skill in the art for the infant formula as taught by Kuslys to comprise a calcium to phosphorus weight ratio of about 1.4 and a Na/K ratio of about 0.4mmol in view of Wilson. One of ordinary skill in the art would have been motivated to use the calcium to phosphorus weight ratio and the Ma/K molar ratio as taught by Wilson, as Wilson teaches that the ratios provide for a preferred infant formula, and as the infant formula composition of Wilson contain all the vitamins and minerals considered to be essential to the daily diet and as Kuslys teaches that the infant formula may comprise ingredients so that it is nutritionally complete (page 6 lines 32-35). Furthermore, to include and vary the amount of nutrients would have been obvious and routine determination to one of ordinary skill in the art based on the nutritional effect of the final food product.

Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1), further in view of the combination of Holm, Finn (Gut Health November 2001 pages 1-28) and Ishibashi et al (Bifidobacteria: their significance in human intestinal health Mal J Nutr 3, pages 149-159, 1997).

Kuslys in view of Hoey teaches of an infant formula comprising probiotic Bifidobacterium longum and Lactobacillus paracasei rhamnosus GG, as discussed above.

Kuslys is silent to the bifodobacteria longum as the BB536 strain as recited in claims 4 and 7.

Holm teaches probiotic foods improve the gut microbiota and through this human health (page 4). Holm teaches that there are a limited number of commercially available probiotics, including Lactobacillus paracasei rhamnosus GG (L. Rhamnosus GG) and Bifidobacterium Longum consisting of BB 536 (B. Longum BB 536) and SBT-2928 (page 14). Holm teaches that the knowledge of health benefits of probiotics is increasing rapidly and that (L. Rhamnosus) was known to assist in the modulation of the immune system and B. longum was known to have anti tumor properties (pages 15-16).

Ishibashi et el (Ishibashi) teaches that the number of bifidobacteria in bottle fed infants is lower than that in breast fed infants (page 150). Ishibashi teaches that infants administered B. longum BB536 has enhanced early colonization of bifidobacteria and formation of bifidobacteria flora, accompanied by reduction of nectrotizing enterocolitis and other intestinal tract infections (page 153).

Regarding the bifodobacteria longum as the BB536 strain, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the B. longum as taught by Kuslys in view of Hoey to be either BB536 or SBT-2928 as the strands of probiotics which are commercially available for foods is limited and that is the selection for B. longum as taught by Holms. One would have been further motivated for the B. longum to be BB536 in order to form a product which would enhance the early colonization of bifidobacteria and formation of bifidobacteria flora in the infant and promote a reduction of nectrotizing enterocolitis and other intestinal tract infections as taught by Ishibashi.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslys et al (WO 01/22837) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1), further in view of Kratky et al (EP 01048226 A1).

Kuslys teaches of an infant formula comprising a source of sweet whey protein wherein the proteins are not hydrolyzed or are hydrolysed, as discussed above.

Kuslys is silent to the protein as partially hydrolysed as recited in claim 9.

Kratky et al (Kratky) teaches of an infant formula (abstract) comprising a source of lipids comprising fish oil (paragraph 0024), a source of carbohydrates (paragraph 0023), and a source of sweet whey protein from which the casino-glyco-macropeptide (CGMP) has been removed (paragraph 0017) wherein the protein is less than 2g/100kcal, including at about 1.8g/100kcal (paragraph 0028). Kratky teaches that the protein fraction can be hydrolyzed or partially hydrolysised, i.e. less hydrolyzed, in order to prevent allergic reactions in infants and make the protein easier to digest (paragraph 0018).

Regarding the protein as partially hydrolyzed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to partially hydrolyze the protein of the infant formula of Kuslys in order for the protein to be more allergenic friendly and easier to digest as taught by Kratky.

Claims 1-3, 5, 6, 9-14, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratky et al (EP 01048226 A1) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1).

Kratky et al (Kratky) teaches of an infant formula (abstract) comprising a source of lipids comprising fish oil (paragraph 0024) which includes the Long Chain Polyunsaturated Fatty Acid (LC-PUFA) comprising docosahexaenoic acid (DHA), a source of carbohydrates (paragraph 0023), a source of sweet whey protein which is modified by the removal of the casino-glyco-macropeptide (CGMP) (paragraph 0017) wherein the protein is less than 2g/100kcal, including at about 1.8g/100kcal (paragraph 0028), other beneficial substances so that it contains adequate nutrients to sustain healthy human life (paragraphs 0027 and 0032), water, and salts which when combined with water formed electrolytes, including sodium, calcium, magnesium, chloride, and potassium (paragraphs 0030 and 0032). Kratky teaches that the protein comprises

about 97-98.5% whey protein (paragraph 0009). Kratky teaches that the protein can be less hydrolyzed, thus teaching that the protein is partially hydrolyzed (paragraph 0018).

Kratky is silent to the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobaceria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG as recited in claim 5, to the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1, and an Na/K ratio of around 0.4mmol as recited in claim 14.

Van Hoey-De-Boer et al (Hoey) teaches that an infant formula with health promoting action is formed with probiotics Bifidobacterium including Bifidobacterium Longum (B. longum) and a Lactobacillus strain including Lactobacillus rhamnosus GG (Lactobacillus paracasei rhamnosus GG) (abstract and paragraphs 0004, 0005, 0014, and 0018). Hoey teaches that the preparation aids in the prevention and treatment of disorders of the gastrointestinal tract (paragraph 0001).

Wilson teaches of a nutritional composition for inclusion in infant formulas (abstract and paragraph 0018). Wilson teaches that infant formulas suitable for use should contain all vitamins and minerals considered to be essential in the daily diet (paragraph 0019). Wilson teaches that a preferred infant formula comprises 460mg of calcium and 333mg of phosphorus and thus a calcium to phosphorus weight ratio of about 1.4 and 160mg of sodium which is about 6.96mmol of sodium and 650mg of potassium which is about 16.62mmol of potassium, and thus an Na/K ratio of about 0.4mmol (paragraph 0020).

Regarding the formula as containing a probiotic as recited in claim 1, wherein the probiotic is Bifidobaceria as recited in claims 3 and 6, and/or wherein the probiotic is Lactobacillus as recited in claims 3 and 6, preferably Lactobacillus paracasei rhamnosus GG, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the probiotics Bifidobaceria and Lactobacillus paracasei rhamnosus GG in the composition of Kratky in view of Hoey in order to form an infant formula which aids in the prevention and treatment of disorders of the gastrointestinal tract as taught by Hoey, thus promoting better infantile health.

Regarding the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 and an Na/K ratio of around 0.4mmol, it would have been obvious to one of ordinary skill in the art for the infant formula as taught by Kratky to comprise a calcium to phosphorus weight ratio of about 1.4 and a Na/K ratio of about 0.4mmol in view of Wilson. One of ordinary skill in the art would have been motivated to use the calcium to phosphorus weight ratio and the Ma/K molar ratio as taught by Wilson, as Wilson teaches that the ratios provide for a preferred infant formula, and as the infant formula composition of Wilson contain all the vitamins and minerals considered to be essential to the daily diet and as Kratky teaches that the infant formula may comprise ingredients so that it is nutritionally complete (paragraphs 0027 and 0030). Furthermore, to include and vary the amount of nutrients would have been obvious and routine determination to one of ordinary skill in the art based on the nutritional effect of the final food product.

Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kratky et al (EP 01048226 A1) in view of Van Hoey-De-Boer et al (EP 0904784 A1) and Wilson (US 2003/0060445 A1), further in view of the combination of Holm, Finn (Gut Health November 2001 pages 1-28) and Ishibashi et al (Bifidobacteria: their significance in human intestinal health Mal J Nutr 3, pages 149-159, 1997).

Kratky in view of Hoey teaches of an infant formula comprising probiotic Bifidobacterium longum and Lactobacillus paracasei rhamnosus GG, as discussed above.

Kratky is silent to the bifodobacteria longum as the BB536 strain as recited in claims 4 and 7.

Holm teaches probiotic foods improve the gut microbiota and through this human health (page 4). Holm teaches that there are a limited number of commercially available probiotics, including Lactobacillus paracasei rhamnosus GG (L. Rhamnosus GG) and Bifidobacterium Longum consisting of BB 536 (B. Longum BB 536) and SBT-2928 (page 14). Holm teaches that the knowledge of health benefits of probiotics is

increasing rapidly and that (L. Rhamnosus) was known to assist in the modulation of the immune system and B. longum was known to have anti tumor properties (pages 15-16).

Ishibashi et el (Ishibashi) teaches that the number of bifidobacteria in bottle fed infants is lower than that in breast fed infants (page 150). Ishibashi teaches that infants administered B. longum BB536 has enhanced early colonization of bifidobacteria and formation of bifidobacteria flora, accompanied by reduction of nectrotizing enterocolitis and other intestinal tract infections (page 153).

Regarding the bifodobacteria longum as the BB536 strain, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the B. longum as taught by Kratky in view of Hoey to be either BB536 or SBT-2928 as the strands of probiotics which are commercially available for foods is limited and that is the selection for B. longum as taught by Holms. One would have been further motivated for the B. longum to be BB536 in order to form a product which would enhance the early colonization of bifidobacteria and formation of bifidobacteria flora in the infant and promote a reduction of nectrotizing enterocolitis and other intestinal tract infections as taught by Ishibashi.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional obvious-type double patenting rejection of claims 1-7, 10-13, and 22-25 as being unpatentable over claims 1, 6-13, 20 of copending Application No. 10/564,805 ('805) as amended March 2, 2009 has been withdrawn in light of applicant's amendments made June 18, 2010; specifically '805 does not claim a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in instant claim 1.

The provisional obvious-type double patenting rejection of claims 8 and 14 as being unpatentable over claims 1, 6-13, 20 of copending Application No. 10/564,805 ('805) as amended March 2, 2009, further in view of Kuslys et al (WO 01/22837) has been withdrawn in light of applicant's amendments made June 18, 2010; specifically '805 does not claim a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in instant claim 1 and an NA/K ratio around 0.4mmol as recited in instant claim 14.

The provisional obvious-type double patenting rejection of claims 9 and 14 as being unpatentable over claims 1, 6-13, 20 of copending Application No. 10/564,805 ('805) as amended March 2, 2009 further in view of Kratky et al (EP 01048226 A1) has been withdrawn in light of applicant's amendments made June 18, 2010; specifically '805 does not claim a calcium/phosphorus weight ratio ranging between 1.4 and 3 as

recited in instant claim 1 and an NA/K ratio around 0.4mmol as recited in instant claim 14.

Claims 1-7, 10-14, and 22-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-13, 20 of copending Application No. 10/564,805 ('805) as amended March 2, 2009 in view of Wilson (US 2003/0060445 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '805 encompass the instantly claimed invention, including claiming an infant or follow on formula comprising a source of carbohydrates, a source of lipids, including a LC-PUFA comprising DHA, probiotics including Lactobcaillus paracasei rhamnosus GG and Bifidobacterium longum BB 536, and at least 40%, preferably at least 60% of the proteins as modified sweet whey proteins with no or reduced CGMP, wherein the protein is present in a maximum proportion of 2g/100kcal, preferably 1.8-1.85g/100kcal. The only difference is '805 does not claim the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 as recited in claim 1 and an Na/K ratio of around 0.4mmol as recited in claim 14.

Wilson teaches of a nutritional composition for inclusion in infant formulas (abstract and paragraph 0018). Wilson teaches that infant formulas suitable for use should contain all vitamins and minerals considered to be essential in the daily diet (paragraph 0019). Wilson teaches that a preferred infant formula comprises 460mg of calcium and 333mg of phosphorus and thus a calcium to phosphorus weight ratio of about 1.4 and 160mg of sodium which is about 6.96mmol of sodium and 650mg of potassium which is about 16.62mmol of potassium, and thus an Na/K ratio of about 0.4mmol (paragraph 0020).

Regarding the formula as comprising a calcium/phosphorus weight ratio ranging between 1.4 and 3 and an Na/K ratio of around 0.4mmol, it would have been obvious to one of ordinary skill in the art for the infant formula as claimed by '805 to comprise a calcium to phosphorus weight ratio of about 1.4 and a Na/K ratio of about 0.4mmol in view of Wilson. One of ordinary skill in the art would have been motivated to use the

calcium to phosphorus weight ratio and the Ma/K molar ratio as taught by Wilson, as Wilson teaches that the ratios provide for a preferred infant formula, and as the infant formula composition of Wilson contain all the vitamins and minerals considered to be essential to the daily diet and as '805 claims that the infant formula may comprise ingredients so that it is nutritionally complete. Furthermore, to include and vary the amount of nutrients would have been obvious and routine determination to one of ordinary skill in the art based on the nutritional effect of the final food product.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 8 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-13, 20 of copending Application No. 10/564,805 ('805) as amended March 2, 2009 in view of Wilson (US 2003/0060445 A1), further in view of Kuslys et al (WO 01/22837). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '805 encompass the instantly claimed invention as discussed above. The only difference is '805 does not claim the protein as intact as recited in claim 8, or the formula as having a low amount of electrolytes as recited in claim 14.

Kuslys teaches of an infant formula (page 2 lines 15-16) comprising a source of lipids comprising fish oil (page 6 lines 14-23), a source of carbohydrates (page 6 lines 6-13), a source of sweet whey protein from which the casino-glyco-macropeptide (CGMP) has been removed (page 2 lines 35 and 36) wherein the protein is at about 1.8g/100kcal (page 3 lines 5-9), other beneficial substances (page 7 lines 28-29), water, and salts which when combined with water formed electrolytes, including sodium, calcium, magnesium, chloride, and potassium (page 7 lines 12-22 and page 8 lines 1-2). Kuslys teaches that the protein can be hydrolyzed or non-hydrolyzed (page 3 lines 21-22). Kuslys teaches that the proteins are not hydrolyzed, and as hydrolysis is the process of breaking down a molecule, one of ordinary skill in the art would expect that the non hydrolyzed proteins as taught by Kuslys are intact as recited in claim 8. Refer

specifically to page 3 lines 21-22. Kuslys teaches that the amount of vitamins and thus electrolytes varies depending on the infant population (page 7 lines 12-22).

Regarding the protein as intact, as Kuslys teaches of a similar infant formula to that as claimed in '805 and as Kuslys teaches that the protein is not hydrolyzed and is intact, it would have been obvious to one of ordinary skill in the art at the time the invention was made for the protein to remain intact and not hydrolyzed as is known in the formula art as taught by Kuslys in order to use compositional ingredients that required less processing, thus saving time and money on equipment and manual labor. To do so would have been obvious and common sense to one of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 9 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6-13, 20 of copending Application No. 10/564,805 ('805) as amended March 2, 2009 in view of Wilson (US 2003/0060445 A1), further in view of Kratky et al (EP 01048226 A1). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '805 encompass the instantly claimed invention as discussed above. The only difference is '805 does not claim the protein as partially hydrolyzed as recited in claim 9.

Kratky teaches of an infant formula (abstract) comprising a source of lipids comprising fish oil (paragraph 0024), a source of carbohydrates (paragraph 0023), and a source of sweet whey protein from which the casino-glyco-macropeptide (CGMP) has been removed (paragraph 0017) wherein the protein is less than 2g/100kcal, including at about 1.8g/100kcal (paragraph 0028). Kratky teaches that the protein fraction can be hydrolyzed or partially hydrolysised, i.e. less hydrolyzed, in order to prevent allergic reactions in infants and make the protein easier to digest (paragraph 0018). Kratky teaches that the amount of vitamins and thus electrolytes varies depending on the infant population (paragraph 0030).

Regarding the protein as partially hydrolyzed, it would have been obvious to one of ordinary skill in the art at the time the invention was made to at least partially hydrolyze the protein of the infant formula of '805 in order for the protein to be more allergenic friendly and easier to digest as taught by Kratky.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to the prior art rejections have been considered but are moot in view of the new ground(s) of rejection; Applicant argues that the newly added limitations have not been taught by the references; The limitations have been addressed in the new rejection above as necessitated by the amendment.

Applicant's arguments with respect to the provisional double patenting rejections have been fully considered but they are not persuasive. Applicant argues that if allowable subject matter is indicated, the applicant will consider the filling of a terminal disclaimer. This is not convincing to withdraw the rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Mueller et al (US 4,216,236) teaches that in an infant formula, a sufficient quantity of phosphorus should be present for the calcium phosphorus ratio by weight to be at least 1.4 (abstract and column 2 lines 21-24).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KELLY BEKKER whose telephone number is (571)272-2739. The examiner can normally be reached on Monday through Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kelly Bekker/
Examiner
Art Unit 1781